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10/539,332

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Eran Lavi

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EXAMINER

PATEL, TARLA R

ART UNIT

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| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/539,332 | Applicant(s) LAVI ET AL. | |
| | Examiner Tarla R. Patel | Art Unit 3772 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 14-45 is/are rejected.
- 7) ☒ Claim(s) 6 and 8-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/15/05 and 5/1/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The Information disclosure statement (IDS) submitted on 6/15/05 and 5/1/06 is acknowledged by Examiner. The IDS meets the requirements of 37 CFR 1.97 and 1.98 and therefore the references there in have been considered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of Application No. ISRAEL 153451 has been received.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Therefore, the reservoir , electronic component and circuitry must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of

the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 17-26 and 40-45 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to claims 17 and 23-26 and 40-44, the specification as originally filed does not adequately describe or depict in the drawings how or where the device has a reservoir recess or rib that holds a material, such a pharmaceutically active agent, beneficial agent, or edible agent, and the agent is or are held in or on part of the reservoir.

Also with respect to claims 18, 19, 20-22 and 42-45, the written description does not adequately describe or depict the device including a control means that includes at least one electronic component and circuitry, nor how the reservoir is suitable for housing a measuring a control means, wherein the control and measuring means measures or controls electric current and/or saliva secretion in the mouth.

Thus, it is unclear how the beneficial or edible material is to be delivered by one of the group defining means for temperature activation, moisture

activation, timed release, or control means by at least one electronic component and circuitry. Further, the written description does not provide specific structure to perform these means.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5,7,14-16, 27-31,33-37, 39 are rejected under 35

U.S.C. 102(b) as being anticipated by Berbersen (4,898,535).

Bergersen discloses a self opening device or device for separating between the upper and lower jaws comprising at least one substantially U-shaped rib (38) and a deformable member associated therewith such that member gradually changes its shape when a pressure is applied on at least one rib by the jaws. It is inherent that device changes its shape, since device is made of plastic (column 1 lines 45-48).

With respect to claim 2, the device is a protection device which prevents a self-inflicting or externally inflicted injury, since it cover the jaws it inherently prevents injury.

With respect to claim 3, the device is capable to suppressing upper airway resistance syndrome, since it permits the user to breathe through the opening (column 2 lines 65-68).

With respect to claims 4 and 5, the device comprises two U-shaped ribs (38,40) having a lingual (18) and buccal (16) side, each of ribs having a curvature corresponding to the curvature of a dental arch and subtending a majority of its length (see fig 1); two support units attached at each posterior end (34) of a pair of ribs on the lingual side, such that two support units have bilateral symmetry about a plane coincidental with an anteriorly located central position of each of ribs and that each of ribs is separated one from the other (column 1 lines 52-53), at a given point along a rib, by a separation substantially corresponding to an essentially maximum jaw angular opening when support units are not compressed; an upper and a lower tooth receiving means (22,24) for each support unit, each of tooth receiving means extending the entire length of a corresponding support units and adapted to retain posterior teeth, borders of each of tooth

receiving means being defined by a wall of support unit (12) longitudinally protruding from a lingual side of a corresponding tooth receiving means and a portion of a rib longitudinally protruding from the buccal side (column 2 lines 47-49).

With respect to claim 7, each support unit is provided with solid lingual walls (see fig 3).

With respect to claim 14, the tooth receiving means is plurality of chambers (22, 24).

With respect to claims 15 and 27, the central anteriorly disposed portion of each rib is an arcuate member for retaining incisor teeth on the buccal side, since the device has a wall with the central anteriorly disposed portion that is inherently arcuate shaped central anterior and it is capable of being place on a corresponding gum when the device is inserted within the oral cavity.

With respect to claim 28, device is inherently prevent damage to the franulum of a corresponding lip, since device is arcuate in shape.

With respect to claim 30 and 31, device is inherently formed with a centrally and anteriorly airway (open space of device between 38 and 40 in fig 1) for

the release of vomit from the oral cavity between two opposing ribs and two opposing deformable members.

With respect to claim 33-34, device is made of plastics, which is same material for whole, plastics characteristic is to harden after it is formed, which is inherently will have greater yield strength.

With respect to claims 35-37, the limitation "device is disposable and for one time use", "the device is reusable", and "device is packageable", these limitations have been treated as an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the limitation have not been positively claimed, it is inherent that the device of Bergersen can be disposable and for one time use, reusable, and capable of being packaged.

With respect to claim 39, each support unit is configured in such a way and produced from a suitable material (plastic column 1 lines 45-47) so as to follow the movement of the jaws.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berbersen (4,898,535) in view of Kittelsen (5,460,527). Bergersen substantially disclose the invention, see rejection to claims 1-5,7,14-16, 27-37, and 39 above; however Bergersen does not disclose that the device having a handle integrally formed with a rib, longitudinally inwards from the arcuate member.

However Kittelsen teaches a device having a handle (88) integrally formed with a rib, longitudinally inwards from the arcuate member (see fig 2 and 3). At the time of the invention, it would have been an obvious to one having ordinary skill in the art to modify the device of Bergersen having a handle integrally formed with a rib, longitudinally inwards from the corresponding arcuate member as taught by Kittelsen, so the device can be used freely and person does not have to put their hand in the mouth to place the device in between the jaw.

10. Claims 17, 24-26, 40-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) in view of Tyler (6,244,269).

Bergersen substantially disclose the invention, see rejection to claims 1-5, 7, 14-16, 27-37, and 39, Bergersen further teaches a rib or reservoir; however Bergersen does not disclose that the device further comprise at least one reservoir suitable for housing a beneficial or edible material, the beneficial and edible material is a scent or taste additive to the oral cavity, the beneficial or edible material is in the form selected from the group of liquid, aerosol, powder, gas and encapsulated form, each reservoir is a recess formed in the deformable member and a method for delivering material to a subject by providing a device with two U-shaped ribs, connected one end to one another and deformable member positioned between them, fitting each of at least one reservoir with a beneficial or edible material, inserting device into the oral cavity of subject such that deformable member separates and upper set of posterior teeth from lower set and allowing beneficial or edible material to be delivered to the subject upon application of pressure onto deformable member by the jaws.

However Tyler teaches a two piece pliable, edible, flavored mouthpiece (abstract), which can also be made using other materials such as flavored silicone, flavored plastics, (column 5 lines 25-29) and can also include flavored liquid centered (column 3 lines 45-49). At the time invention was made it would have been obvious to one having ordinary skill in the art to use the material of flavored plastic or flavored liquid centered as deformable material in the reservoir of Bergersen, as the material taught by Tyler to have better tasting device.

With respect to claims 40-44, a method of for delivering material to a subject the device of Berbersen and Tyler disclose the structural limitations of the invention (see above). Therefore it would have been obvious to one having ordinary skill in the art to perform the steps of inserting the device into the oral cavity of subject, such that the deformable member separates an upper set of posterior teeth from a corresponding lower set of posterior teeth and allowing beneficial and edible material to be delivered to subject. The edible or beneficial material can be delivered upon application of pressure by the jaws on said device, by the temperature within the oral cavity of the subject being greater than a predetermined value, by moisture level within the oral cavity of the subject being greater than a

predetermined value, or after a predetermined time of having the device inserted into the oral cavity.

11. Claims 18-21 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) and Tyler (6,244,269) further in view of Schaefer et al (5,490,520).

Bergersen and Tyler substantially disclose the invention as claimed, see rejection to claims 17 and 40 above; however, Bergersen and Tyler do not disclose that the beneficial and edible material is delivered to a subject a by control means, which can be one electronic component and circuitry, that the reservoir is suitable for housing the control means, and that the control means controls electric current and /or saliva secretion.

However Schaefer et al teaches a dental appliance for treating bruxism by means of a device including electronic circuitry (abstract). At the time invention was made it would have been obvious to one having ordinary skill in the art to include the control means of electronic circuitry as taught by Schaefer in the device of Bergersen and Tyler device to enhance or measuring the delivery of material to the subject.

12. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) and Tyler (6,244,269) further in view of Kittelsen (5,460,527).

Bergersen and Tyler substantially disclose the invention as claimed, see rejection to claim 17 above; however Bergersen and Tyler do not disclose that the beneficial and edible material is a pharmaceutically active agent. However, Kittelsen teaches a composite bleaching tray having U-shaped base compound of nonsoftening, resilient low compression elastomer, wherein the bleach is a pharmaceutical active agent (abstract). At the time invention was made, it would have been obvious to one having ordinary skill in the art to substitute the composite bleaching agent for the beneficial agent in the device of Bergersen and Tyler to provide a simple device to use for whitening a subject's teeth.

13. Claims 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (4,898,535) in view of Pratt (5,323,787).

Bergersen substantially disclose the invention as claimed, see rejection to claims 1-5,7,14-16, 27-31,33-36, and 39 above; however Bergersen does not disclose that the device is packageable in a container which breaks

upon removal of the device from said container and providing a retaining means for retaining the container in an accessible location.

However, Pratt teaches a custom fitted mouthpiece with storage container (Abstract). At the time invention was made it would have been obvious to one having ordinary skill in the art to use the container keep the Bergersen's device as taught by Pratt to store the device.

Allowable Subject Matter

14. Claims 6, and 8-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The following is a statement of reasons for the indication of allowable subject matter: The subject matter of the independent claims could either not be found or was not suggested in the prior art of record. The subject matter not found was the device having plurality of longitudinally disposed fins which are compressible upon application of jaw forces and which can return to their original dimensions following the relaxation of the jaw muscles, each fin comprises a first portion proximate to the first rib, a second portion proximate to a second rib, and a central arcuate portion connecting first portion and second portion, first and second portions being

symmetrical about a plane which passes through a junction connecting first and second ribs and which separates a support unit into two separate sections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-F 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TP

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